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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,219	04/16/2004	Alfons Bosman	BJS-2551-149	7081

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
03/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,219	BOSMAN ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed December 27, 2007 in response to the Office Action of July 27, 2007 is acknowledged and has been entered. Applicant's request to rejoin process claim 21 has been considered but is untimely. Until all of the elected subject matter is deemed allowable, rejoinder of non-elected inventions is not appropriate. Claim 21 remains withdrawn from consideration as being directed to non-elected subject matter. Claims 12-20 and 22-33 are under examination.

Foreign Priority

Applicant's submission of the foreign priority document EP 94870132 is acknowledged. The claims of the present Application are entitled to the priority date of 7/29/1994.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Rejection of claims 12-20, 22-33 under 35 U.S.C. 103(a) as being unpatentable over Maertens (WO 96/04385, IDS of 8/25/2007) in view of Hofstaetter et al. (Vax Sang. Vol. 45, p. 155-165, IDS of 6/11/2007) **is withdrawn** because Maertens (WO 96/04385) does not constitute prior art for the present Application. Maertens (WO 96/04385) document is a priority document for the present Application, which is the PCT/EP95/03031.

It noted that Applicants argue that Maertens (WO 96/04385) does not teach reversibly blocking cysteine residues of the HCV envelope protein. The Office respectfully disagrees with Applicants arguments. Maertens (WO 96/04385) does teach reversible protection of cysteine residues of HCV because Martens teaches blocking cysteine residues of HCV protein with

Glutathione (GSH) (see page 14, lines 30-32) which causes **reversible** protection of cysteine residues as disclosed in the present Application in Example 3. Thus because Maertens (WO 96/04385) teaches the limitation of reversible protection of cysteine residues of HCV the present claims are given priority of 7/31/1995 and therefore Martens does not constitute prior art.

New Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 17 under 35 U.S.C. 112, first paragraph, is reinstated (see Office action of January 22, 2007). The specification, while being enabling for an immunogenic composition comprising isolated HCV envelope protein or functionally equivalent part thereof, does not reasonably provide enablement for a medicament comprising isolated HCV envelope protein or functionally equivalent part thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim is drawn to a medicament comprising isolated HCV envelope protein or functionally equivalent part thereof. A medicament can be interpreted to be a drug; a drug by definition is an agent intentioned for the use in the diagnostics, mitigation, treatment, cure, or prevention of disease in humans or in other animals. Pharmaceutical therapies in the absence of *in vivo* clinical data are unpredictable. The specification does not set forth sufficient teachings to allow one skilled in the art to use the claimed medicament for treatment or prophylaxis of

infectious diseases. The specification does not provide teachings to establish effective dosages or methods of administration of the claimed recombinant poxvirus treat infections. The specification provides no description or exemplification of how to use the medicament for the prevention, diagnosis, alleviation, treatment, or cure of a disease in the animal to which the substance is administered. No working examples are provided which would provide sufficient guidance to allow one skilled in the art to practice the above embodiments of the invention with a reasonable expectation of success.

The specification speculates generating a vaccine against HCV infection ([0027], [0130], [0188]) while the specification does not provide sufficient enablement for the contemplated vaccines or medicaments comprising HCV envelope proteins. The skilled artisan would have expected that HCV envelope proteins would induce immunogenic immune responses; however the skilled artisan would be required to conduct an undue amount of experimentation in order to determine whether the claimed compositions can be successfully used as medicaments or vaccines.

The instant specification has not taught how to use the HCV envelope proteins as a medicament for treatment or prophylaxis. The specification provides insufficient guidance, which would allow one of skill in the art to predict the efficacy of the claimed medicament with a reasonable expectation of success. As discussed above undue experimentation would be required to practice the claimed invention commensurate with the scope of the claims.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working

examples, the unpredictability of the art, the lack of sufficient guidance in specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-20 and 22-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 16 and 34 of U.S. Patent No. 7,048,930 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to HCV envelope protein comprising reversibly protected cysteine residues and methods of detecting HCV antibodies comprising detecting the complex of an anti-HCV antibody and the HCV envelope protein, and the patented claims are drawn to the HCV envelope protein VLP comprising reversibly chemically modified cysteine

residues and methods of detecting HCV antibodies comprising detecting the complex of an anti-HCV antibody and the HCV envelope protein. The present and the patented claims recite sulfonation as means of reversible protection/modification of cysteine residues. Thus the present claims are obvious over the patented claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen, Ph.D./

Examiner, Art Unit 1648

/Stacy B Chen/

Primary Examiner, Art Unit 1648